K123956

510(K) Summary of Safety and Effectiveness

JAN 25 2013

Submitter: KARL STORZ Endoscopy America Inc.			Date of Preparation: **January 16, 2013**
Sponsor Company Name: KARL STORZ Endoscopy America Inc. (KSEA)			**Phone Number:** (424) 218 8322
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City: El Segundo	**State:** California	**Country:** USA	**Zip Code:** 90245
Contact Name: Shiven Gandhi			
Contact Tittle: Regulatory Affairs Associate			
Email Address: shiven.gandhi@karlstorz.com			
Manufacturing Company Name: Karl Storz GmbH & Co. KG			
Street Address: Mittelstrasse 8			
City: Tuttlingen	**State/Province:** Baden-Wurttemburg	**Country:** Germany	**Zip Code:** 78532
Trade Name: Power LED 175			**Model Number:** 20161420-1
Common Name: LED Light source			**Classification Name:** FCW – Light Source, Fiber Optic, Routine NTN – LED Light Source

Information about devices to which Substantial Equivalence is claimed:

510 (K) Number	Trade/ Proprietary Name/Model Number	Manufacturer/
K091968	LED NOVA 100 Cold Light Fountain	Karl Storz GmbH & Co. KG
K962595	300 Watt Xenon Light Source	Karl Storz GmbH & Co. KG

Introduction:

Device Trade Name:	Power LED 175
Common Name:	Light source, Fiber Optic, Routine
Classification Name:	Endoscope and accessories
Regulation Number:	21 CFR 876.1500
Product Code:	FCW, NTN

Device Description:

The power LED 175 is a high power medical cold light source used for endoscopic diagnostic and surgical procedures. The device can be controlled via buttons on the front panel or via SCB (STORZ Communication Bus). This device provides high light intensity at low power consumption with intelligent cooling concept for minimal noise emission. This device includes a cold light source power LED 175, power cord, and the 100 cm SCB connection cable. The light is transmitted through an optical cable and a scope to illuminate surgical sites during minimally invasive surgical procedures.

Indication for Use

Cold light sources are designed to supply light for endoscopic diagnostic and surgical procedures.

Technological Characteristics:

Parameter	Power LED 175 Cold Light Fountain (Subject Device)	LED NOVA 100 Cold Light Fountain (Predicate Device)	300 Watt Xenon Light Source (Predicate Device)
Applicant	KARL STORZ Endoscopy America Inc.	KARL STORZ Endoscopy America Inc.	KARL STORZ Endoscopy America Inc.
510(k) number	K123956	K091968	K962595
Type of Device	Light Source	Light Source	Light Source
Intended Use	Cold light sources are designed to supply light for endoscopic diagnostic and surgical procedures.	Used as a light source in conjunction with rigid and flexible endoscopes as well as other light providing instruments to illuminate the operating field during minimally invasive endoscopic surgical procedures	The device is designed to supply light for endoscopic diagnostic and surgical procedures.
Lamp Type	LED	LED	Xenon
Color Temperature	6500 K	5600 K	6000 K
Used With	Fluid Optic or Fluid Light Cable, Rigid or Flexible Endoscope	Fluid Optic or Fluid Light Cable, Rigid or Flexible Endoscope	Fluid Optic or Fluid Light Cable, Rigid or Flexible Endoscope

Performing Testing

The performance testing to verify light output of Power LED 175 was done as per the Comparative Bench Testing attached in Enclosure # 6. Design Verification Testing (DVT) demonstrates that the device functions as it is intended and its performance does not raise any new issues of safety and effectiveness. Software verification was done and is attached in Enclosure # 5.17 Performance standards under section 514 of the Code of Federal Regulations Title 21 have not been developed for this device however the manufacturer complies with the following voluntary standards:

- IEC 60601-1 Medical Electrical Equipment, Part 1- General Safety Requirements
- IEC 60601-1-2:2001 (CISPR 11 Class B) - Electromagnetic Compatibility
- IEC 60601-2-18 Medical Electrical Equipment, Part 2-18 – Particular requirements for the basic safety and essential performance of endoscopic equipment

Summary of Substantial Equivalence:

The Power LED 175 is substantially equivalent to the existing 510(k) cleared devices on the market i.e. KARL STORZ LED NOVA 100 Cold Light Fountain (K091968 cleared September 14, 2009) and KARL STORZ 300 Watt Xenon Light Source (K962595 cleared September 4, 1996). The indication for use of the Power LED 175 is identical to the predicate devices. The Power LED 175 does not incorporate any special technology or characteristics when compared to its predicate devices.

Conclusion:

The Karl Storz Power LED 175 is substantially equivalent to the predicate device(s) mentioned above and the non-clinical performance testing demonstrates that the device is as safe and effective and performs as well as or better than the legally marketed devices

Contact:

Shiven Gandhi 01/16/2013

Shiven Gandhi **Date:**

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Karl Storz Endoscopy-America, Incorporated
% Mr. Shiven Gandhi
Regulatory Affairs Associate
2151 East Grand Avenue
El Segundo, California 90245-5017

January 25, 2013

Re: K123956
Trade/Device Name: Power LED 175 Cold Light Fountain
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FCW, NTN
Dated: December 18, 2012
Received: December 12, 2012

Dear Mr. Gandhi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use:

510(k) Number: K123956

Device Name: Power LED 175 Cold Light Fountain

Indication for use: Cold light sources are designed to supply light for endoscopic diagnostic and surgical procedures.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801.109 i.e. Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
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(Division Sign-Off) for mdm
Division of Surgical Devices
510(k) Number K123956